Administrative Supplements for NCI P30 Cancer Center Grants to Facilitate the Development of Standardized Electronic Treatment Plan Builds for NCI-Supported Clinical Trials Applicable Across Clinical Research Sites

Background

All NCI-supported Cancer Centers utilize electronic health records (EHRs) to support the delivery of standard-of-care and investigational diagnostic and treatment programs. These health record systems not only provide a standardized approach to the care plans used for all patients (both inpatients and outpatients) treated at these sites, but are also critical components of the financial infrastructure used to recover clinical charges from third party payers for services rendered. While the EHR-based care plans for routine therapies provide quality control through the standardization of care processes, such as the administration of pharmaceuticals (chemo- and immunotherapy, for example), these procedures may vary considerably from one health care provider to another, even when the same EHR is in place at both organizations. To support clinical trials that employ investigational agents, furthermore, each electronic treatment plan must be built from scratch, whether or not the trial targets a patient population suffering from a rare tumor (which might have very low accrual) or a common malignancy. The complexities surrounding development of treatment plans that utilize non-FDA approved therapeutics also require the programming into treatment plans of essential ancillary procedures that change from study to study, and site to site; they must also be tailored to produce clinical charges that reflect only those permitted by either governmental or commercial insurers. The more arms incorporated into the study (as would occur in a basket trial), the more costly the treatment plan builds become. Multisite studies, like those performed by NCI's clinical trials networks, thus require repetitive efforts to modify different instances of EHR systems present across potentially hundreds of institutions. It is clear that this process has contributed to prolonging the activation times as well as increasing the cost of conducting NCI-supported clinical trials.

Purpose and Goals

The goal of this NCI initiative is to develop processes across multiple NCI-supported Cancer Centers and community sites that will facilitate the development of single instances of EHR clinical trial treatment plans that can be deployed at multiple institutions in support of NCI-sponsored network studies. The hypothesis to be investigated is whether a small consortium of

clinical trials sites that have substantive histories of patient accrual to NCI trials, collaborating with an established EHR vendor and the NCI, can develop methods to standardize workflows, drug formularies, drug administration procedures, and laboratory requirements leading to the creation of the components for a standardized electronic clinical trial build system. The aims of this consortium are: 1) to identify all of the tasks currently performed by EHR investigational treatment plans (SOPs, policies, and workflows) and to define differences among these SOPs at the individual member sites of the consortium, 2) to standardize the processes within each task where possible and document differences that would require modifications across sites, 3) to develop a master assessment of EHR treatment plan modules that could be reused so as to perform components of the same research protocol tasks at multiple sites while maintaining compliance with the requirements of member organizations of the consortium, 4) to build standardized electronic clinical trial build modules that could undergo pilot testing at each institution for a specified group of NCI-sponsored clinical trials, 5) to facilitate development of metrics for the new EHR processes that can demonstrate whether more consistent patient care, reduced medication errors, and fewer adverse events result from a standardized approach to clinical trial build modules, 6) to increase interoperability of de-identified research data for regulatory reporting and translational research, and 7) to organize a leadership structure for the consortium that will work with the NCI and an EHR provider to oversee this initiative so as to assure that adequate progress is made toward the ultimate goal of creating a fully automated electronic clinical trial build system that will facilitate the activation of clinical trials across all NCI-supported networks.

Eligibility and Budget

- This supplement program is limited to institutions holding NCI P30 Cancer Center Core grants; these grants must not be in an extension at the time of award.
- The Cancer Centers (CCs) must have the capability to subcontract resources to potential partners, including community clinical trial sites currently holding awards from NCI's NCORP program.
- Only one supplement request will be permitted per NCI CC.
- Each potential member of the proposed consortium must demonstrate its current access to, integration of, and experience with a major EHR vendor's product in the context of their clinical and research activities.

- Applicants must demonstrate that their EHR vendor will participate in the activities of the consortium to provide its expertise in support of the consortium's overarching goals.
- Each member must demonstrate its active participation in and accrual to NCI network clinical trials.
- Each member of the consortium must demonstrate its advanced capabilities in information technology (IT) and analytics, as well as the presence of a centralized IT infrastructure at the institution that will commit the personnel necessary for this project, including EHR build staff. The sites must also demonstrate the presence of the regulatory and investigational drug pharmacy staff necessary for this project.
- **Budget**: Approximately 4-5 administrative supplements will be awarded. One supplement request of $500,000 total costs for a site that will serve as the coordinating center for a consortium will be awarded. Three to four supplements for the member sites of $300,000 total costs each will be awarded. The project period is for one year. Progress will be monitored by regular meetings of the consortium members with the NCI and the EHR vender.

Requirements

- Individual proposals from a CC must describe the other CC/NCORP members of the consortium, the CC that will serve as the coordinating center, and how the consortium members will interactively function to achieve the goals of this initiative.
- Each consortium must identify an oncologist to serve as the overall director of the project as well as that individual's experience and qualifications for the development of new approaches to enhance electronic clinical trial build systems for EHRs. In addition to the overall director of the coordinating center site, each institution participating in the consortium must identify an experienced oncologic clinical trialist with expertise in EHRs and clinical trial build systems who will coordinate activities at that site.
- The EHR/IT staff at each site must be identified and their roles in the project specified. The Investigational Drug Pharmacy, research nursing, and project management staff for the project should also be described.
- Each applicant CC must provide a letter of support from their Cancer Center Director/Chief Scientific Officer/Chief Research Administrator/or Chief Information Officer as appropriate demonstrating the commitment of the CC to the project.

Application Submission Format

Applications should be submitted as a signed, scanned PDF to James Doroshow, M.D. (doroshoj@mail.nih.gov) and Monika Sarna (msarna@mail.nih.gov) no later than 5 PM local time on July 31, 2020. Email confirmation of application receipt by Monika Sarna must be obtained to be officially considered and evaluated.

Requests must include the following:

- The standard PHS 398 Face Page
- A detailed Budget and Budget Justification. Describe the qualifications of the individual(s) who will conduct the work. Briefly elaborate on each person's CV in the budget justification.
- NIH Biographical Sketches for key personnel proposed in the supplement.
- Summary of the Project, not to exceed six (6) pages; references are excluded from the page lime; no appendices, please, other than the specific requested letters of support.

The 6 page summary must provide evidence of the following:

- Appropriate leadership and team with experience in the development of electronic clinical trial build systems
- Appropriate expertise and infrastructure to support analysis of EHR system requirements for investigational trials
- Appropriate expertise in all aspects of the conduct of investigational clinical trials
- Support from the EHR provider to participate in this effort as previously described
- Written support for this project from officials currently overseeing the institution's EHR and clinical research infrastructures
- Evidence of substantive participation in and accrual to NCI clinical trials network (NCTN/ETCTN/NCORP) clinical trials
- Detailed description of the process and procedures that the consortium will use to standardize all elements of current EHR research treatment plan builds leading ultimately to the development of SOPs and standardized modules that could be shared across institutions utilizing EHRs from the same vendor. Define a timeline and process map for the steps needed (and the tools to be developed) that will be required to initiate a pilot

study that will evaluate the new processes across a selection of NCI-supported clinical trials at all of the member institutions of the consortium.

NCI Evaluation of Supplement Requests

Administrative supplements do not receive peer review. Instead, NCI staff with expertise in clinical trials infrastructure will evaluate supplement requests to determine overall merit. Proposals will be reviewed for quality and for responsiveness to application criteria outlined in the requirements for the six page summary described above.

Reporting Requirements

As part of the progress report for the parent CC grant, information must be included on what has been accomplished by the administrative supplement. Project Directors will participate in calls where they will be expected to present their progress and findings to NCI. Award recipients are expected to provide data to NCI evaluators when requested.

Questions

For technical inquiries (including eligibility), please contact your cancer center support grant administrator or your NCI Program Official. For inquiries about the scientific objectives and goals, please contact: James H. Doroshow, M.D., Director, Division of Cancer Treatment and Diagnosis, NCI (doroshoj@mail.nih.gov).